

**HIGHER MEDICAL TRAINING**

**CURRICULUM**

**FOR**

**CLINICAL PHARMACOLOGY  
& THERAPEUTICS**

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## **INTRODUCTION**

Clinical pharmacology and Therapeutics encompasses all aspects of drug therapy in clinical practice, from basic mechanisms to practical prescribing. Training in research and research methods equips clinical pharmacologists to plan, conduct, and interpret experimental and observational studies of drug treatment, and to contribute to safe and effective drug use for the community. The clinical emphasis on rational therapeutics, drug safety, and poisoning provides the skills to care for individual patients with complex therapeutic problems

### **Entry Requirements**

Applicants for Higher Medical Training (HMT) must have completed a minimum of two years General Professional Training (GPT) in approved posts and will usually have obtained the MRCP (UK) or (I). Those wishing to enter training in Clinical Pharmacology and Therapeutics with other higher medical qualifications are encouraged to contact the JCHMT. Innovative programmes combining CPT with a variety of medical specialties are being actively pursued.

GPT is defined as follows:

- a minimum of 2 years in approved posts with direct involvement in patient care and offering a wide range of experience in a variety of specialties
- 18 months of the 2 years must be spent in posts providing experience in the admission and early follow-up of acute emergencies
- at least 6 of these 18 months must be spent on a service or services on which the emergency take is 'unselected'
- 'unselected take' is defined as acute medical intake encompassing the broad generality of medicine ie not restricted to any single or small group of specialties. If any major component of acute medicine (eg cerebrovascular accidents, myocardial infarctions) is excluded from the take, this experience must be obtained in other posts. During the period on 'unselected take' trainees should have an on-call commitment which averages no less than 4 takes per month

Non-UK graduates without the MRCP who compete for HMT posts must provide evidence of appropriate knowledge, training and experience, particularly in the care of acute medical conditions.

### **Duration and Organisation of Training**

The programme of training in CPT occupies four years. Most trainees enter a joint programme with G(I)M or another medical specialty. For those intending to train in General (Internal) Medicine or another medical specialty as well as Clinical Pharmacology and Therapeutics an additional year (or occasionally two additional years) will be required. The first year of a joint programme will comprise experience in General (Internal) Medicine, but should include early experience in Clinical Pharmacology and Therapeutics. Two of the remaining four years will provide methodological experience of clinical and laboratory research, fundamental to the specialist in Clinical Pharmacology and Therapeutics. During this period, one year will be spent in supervised research, and the other year will involve comprehensive training in investigational skills relevant to Clinical Pharmacology and Therapeutics. The remaining two years must be spent in a District General Hospital or a

teaching hospital with DGH facilities, undergoing training for equal periods in General (Internal) Medicine and Clinical Pharmacology and Therapeutics.

Trainees intending to practise in Clinical Pharmacology and Therapeutics and another specialty in addition to, or instead of General (Internal) Medicine, should seek guidance from JCHMT in advance of receiving their NTN on the duration and organisation of their training. It is possible also for a trainee to undertake a programme leading to certification in three specialties. A model programme combining Clinical Pharmacology & Therapeutics, General (Internal) Medicine and Respiratory Medicine and lasting seven years is described in this document. Such programmes must be approved in advance of appointment of a trainee.

HMT will provide experience in both teaching hospital(s), or other major centres with academic activity, and in hospitals with DGH facilities. The programme to which the trainee is appointed will have named consultant trainers (educational supervisors).

### **Research**

One year of supervised research will count towards the overall programme. Some trainees may wish to spend two or three years in research, either before entering HMT (but after obtaining MRCP(UK) or (I)) or by stepping aside from clinical training after entering a programme. This is perfectly acceptable but only one full year will count towards the programme. For those undertaking an extended period of research *after entering a programme* and obtaining their NTN, a limited amount of additional educational credit may be granted at the discretion of the SAC for clinical work relevant to the programme undertaken in the course of research beyond the initial year. This concession does not apply to those undertaking research *prior to entry* to a higher training programme.

### **Investigational skills**

The year that comprises training in investigational skills is necessary because the specialist in Clinical Pharmacology and Therapeutics is expected to guide and direct the clinical assessment of drugs, and requires a broad experience of the investigational methods used in pharmacological research. Necessary skills for the design and ethical conduct of drug investigation in accordance with Good Clinical Practice\* are best acquired through practical experience of pharmacokinetic, interaction and dose ranging studies, studies of efficacy and safety, clinical trials, and pharmacovigilance studies. These skills are frequently sought by local research ethics committees for the effective execution of their function.

\* Good Clinical Practice (GCP) - a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that provides assurance that the data and recorded results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

### **Training Record**

A Training Record will be maintained by the trainee. It will be counter-signed as appropriate by the Educational Supervisors to confirm the satisfactory fulfilment of the required training experience and the acquisition of the competences that are enumerated in the Specialty Curriculum. It will remain the property of the trainee, and must be produced

at the annual assessments

### **Flexible training**

Trainees who are unable to work full-time are entitled to opt for flexible training programmes.

EC Directive 93/16/EEC requires that:

- i Part-time training shall meet the same requirements as full-time training, from which it will differ only in the possibility of limiting participation in medical activities to a period of at least half of that provided for full-time trainees;*
- ii The competent authorities shall ensure that the total duration and quality of part-time training of specialists are not less than those of full-time trainees*

The above provisions must be adhered to. Flexible trainees should undertake a pro rata share of the out of hours duties (including on-call and other out of hours commitments) required of their full-time colleagues in the same programme and at the equivalent stage.

For details of appointment and funding arrangements for flexible trainees, please see the revised 'Guide to Specialist Registrar Training' (February 1998).

### **Assessment**

Assessment of trainees will be based upon the standard format of annual review, including the Penultimate Year Assessment (PYA) to which particular importance attaches. Full details may be found in the Introduction to the JCHMT handbook. The award of the CCST will be based on satisfactory completion of the entire series of annual assessments.

### **Clinical Experience**

The trainee should take an active part in the local clinical service in Clinical Pharmacology and Therapeutics, and in local approaches to rational and cost-effective prescribing.

### **Management Training**

This should include awareness of the organization and function of the National Health Service, and of the relation between purchasers and providers; an understanding of clinical budgeting, personnel management, medical staff employment and complaints procedures; and acquisition of skills in interviewing, written communication, and committee participation.

### **Medical Audit**

The trainee should attend and contribute to regular peer-group audit meetings at which clinical practice and drug therapy are exposed to critical scrutiny.

### **Industrial Experience**

Trainees seeking certification in Clinical Pharmacology and Therapeutics may undertake part of their training in the Pharmaceutical Industry. Approved experience in the Pharmaceutical Industry can be counted towards the overall requirement, giving up to a total of up to one year's credit towards investigational skills training and/or up to one year's credit towards supervised research.

## Curriculum

The tables below outline the curriculum. The degree of knowledge and skills rating alongside each item of subject matter is explained as follows:

<b>Knowledge</b>	<b>1</b>	<b>2</b>	<b>3</b>
	Extensive and detailed knowledge of this subject matter is obligatory..	Be able to explain the principles involved in this subject matter is expected, but detailed, working knowledge is not required.	Recognition of the importance of these subjects is expected.

<b>Skills</b>	<b>A</b>	<b>B</b>	
	The trainee is expected to be able to carry out this activity unaided	The trainee is expected to be able to contribute to this activity as part of a team	

## Drug Action in Man

Objective	Subject Matter	Competence		Teaching/Learning Method	Assessment/evidence of competence
		Knowledge	Skills		
To be able to undertake and interpret early phase studies of drug action in humans	Receptors/enzymes, agonists/activators, antagonists/inhibitors	2		Discussion with senior staff, attendance at lectures/seminars/tutorials especially BPS meetings	Evaluation of published papers/trial protocols
	Structure-activity relationships.	3		Attendance at ethics committees, especially dealing with first into man studies	Evidence of attendance at research meetings
	Dose response relationships.	1		Writing trial protocols	<i>Tests of knowledge</i>
	Principles of pharmacodynamic studies.	2		Writing papers for publication	
	Relationship between pharmacokinetics and pharmacodynamics	1			
	Determination of optimum dose range			A	
	Risk-benefit analysis			B	
	Efficacy and potency	1			
Principles of "first into man" studies	2				

### Clinical Pharmacokinetics

Objectives	Subject matter	Competence		Teaching/learning methods	Assessment /evidence of competence
		Knowledge	Skills		
To use pharmacokinetic principles to optimise drug administration and drug effect	Routes of drug administration	1		Tutored clinical experience	Supervisor assessment
	Factors affecting absorption of drugs	2		Independent Study	Laboratory note-book
	Drug metabolism pathways - Enzyme induction/inhibition	2		Observing assay methods.	<i>Tests of knowledge</i>
	Interpretation of drug concentration in body fluids		A	Performing assay under supervision	
	Definition and interpretation of: Bioavailability Half life AUC Volume of distribution Clearance		B	Applying pharmacokinetic principles to actual assay results - real and simulated.	
	Common methods of drug assay	3		Use of computer programmes to model pharmacokinetic behaviour of drugs.	
	Computer-PK modelling	3			
	Appropriate alterations of therapeutic regimens using understanding of pharmacokinetics of relevant drug			A	

## Rational & Cost Effective Use Of Medicines

Objective	Subject Matter	Competence		Teaching/Learning Method	Method Of Assessment/ evidence of competence
		Knowledge	Skills		
To use drugs rationally and cost-effectively in clinical practice	Critical approach to use of drugs. Choice of drugs based on efficacy, safety, acceptability and cost	1	A	Clinical experience and discussion with supervisor.	Observed practice by trainer or supervisor  Portfolio: Case presentations, audit Report of trainer or chair of DTC Portfolio critical assessment of : <ul style="list-style-type: none"> <li>• DTC presentations</li> <li>• Guidelines produced by trainee</li> <li>• articles submitted for publication</li> </ul> <i>Computer-based assessment e.g. MCQ</i>
	Determinants of drug response in individuals depending on age, sex, genetic background etc.		A	Audit of drug use Case presentations	
To contribute to rational and cost-effective use of medicines within organisations and institutions	Personal formulary	2	B	Participation in writing and development of guidelines Full membership of Drugs and Therapeutics Committee	
	Development of prescribing policies, formularies and guidelines.		B	Seminars, small group teaching Independent reading Formal teaching in seminars	
To define the role of national bodies in ensuring rational and cost-effective use of medicines	Medicines management in hospital and GP settings and at the interface. (eg Drugs and Therapeutics committees).	2	B		
	Skills in membership of such committees. Working with drug budgets.		B		
	Mechanisms and legislation for drug licensing, control and pricing, role of National Institute for Clinical Excellence				

## Evaluation Of The Scientific Literature

Objective	Subject Matter	Competence		Teaching/Learning Method	Assessment/evidence of competence
		Knowledge	Skills		
To Be Able To Critically Evaluate Scientific Publications And To Search The Medical Scientific Literature Using Electronic Databases	The Criteria For Judging Papers, Including Criteria Related To Experimental Design And Analysis. Understanding The Sources Of Bias Including Conflict Of Interest	1	A	Writing Scientific Papers  Involvement in journal article reviewing (supervised)  Preparation of reviews for DTC, Journal clubs and audit meetings.	Supervisor Evaluation Of Competence In Reviewing Process And Electronic Database Searching
	The nature and ethics of peer-review	3		Database Searching Tutorials/ Courses	
	Publication bias Meta-analysis Evidence-based medicine	1			
	Electronic databases such as Medline, Embase and Cochrane	1	A		
	Use Of Expert Reviews Eg Nice, Dtb	1	A		

**Statistics and experimental design**

Objective	Subject Matter	Competence		Teaching/Learning Method	Assessment/evidence of competence
		Knowledge	Skills		
To select and interpret appropriate statistical analysis of experimental data	Biological Variation And Statistical Variance	1		Analysing biological data derived from trainee's research activity	Supervisor Evaluation Of Competence
	Application of appropriate, commonly used statistical tests such as Chi squared analysis, T-testing, simple ANOVA	1	A	Involvement in journal article reviewing (supervised)	<i>Tests of knowledge</i>
	Parametric and non-parametric analysis			Statistics course	
	Application of correlation and regression		A		
	Interpretation of P-values, confidence intervals	1	A		
Actual vs relative risk reduction	1				

## Design and execution of clinical trials

Objective	Subject Matter	Competence		Teaching/Learning Method	Assessment/evidence of competence
		Knowledge	Skills		
To be able to design a clinical trial and write a trial protocol	Types Of Trial Design	1		Involvement In Trial Design, Including Writing Protocols And Ethics Committee Submissions	Ideally should have designed clinical trial and written protocol  <i>Tests of knowledge</i>
	Study Rationale	1			
	Ethics of research in human subjects - informed consent	1		Attendance at ethics committee meetings	
	Understanding the importance of biological variation and sample size in determination of statistical power	1		Courses on GCP	
	Principles of randomisation and use of controls, placebos, and blinding	1			
	Volunteer screening Role of trial monitor Principles of GCP	2	A		
	Design of trial using above knowledge				

## Adverse Drug Reactions

Objective	Subject Matter	Competence		Teaching/Learning Method	Assessment/evidence of competence
		Knowledge	Skills		
To be able to detect and manage adverse reactions due to drugs	Common clinical presentations of adverse drug reactions and appropriate management	1	A	Clinical experience, case discussion, formal teaching in lectures, seminars, and tutorials.	Observation by supervisor <i>Tests of knowledge</i>
	Common adverse effects of widely prescribed drugs	1		Completion of Yellow Cards in appropriate circumstances	
	Types and mechanisms of adverse drug reactions and drug interactions	2			
	The theory of detecting adverse drug reactions - algorithms for deciding whether an adverse reaction has occurred, likelihood of detecting a reaction before marketing.	3			
	Post-marketing surveillance systems	2			

**Socio-political aspects of use of medicine**

Objective	Subject Matter	Competence		Teaching/Learning Method	Assessment/evidence of competence
		Knowledge	Skills		
To describe what determines the pattern of use of medicines in populations.	Factors affecting drug use eg social class, co-morbidity	3		Attachment to units specialising in pharmacoepidemiology or health economics	Observation by supervisor <i>Tests of knowledge</i>
	Public perception of drugs and their use in treating and preventing disease	3		Attendance at courses in pharmacoepidemiology	
	Effect of media on public perception of medicine use	3		Observation at meetings of organisation which determines national drug policy (eg NICE)	
	Role of pharmaceutical industry and government on use of medicines, pricing and public perception of drug use	3			

## Research Ethics

Objective	Subject Matter	Priority		Teaching/Learning Method	Assessment/evidence of competence
		Knowledge	Skills		
To understand the principles of ethical research in human subjects and the process by which this is ensured	Role of ethics committees - Local (Hospital-based)	1		Observation of working of research ethics committees	Evidence of attendance of ethics committee meetings
	Company based MRECs	3		Taught course on ethics / ethics committees	
	Constitution and terms of reference of ethics committees	3			
	International guidelines for ethical research - Declaration of Helsinki ICH guidelines	1			
	Legal position and responsibility of members of ethics committees.	1			
	Legal liability	1			
	Confidentiality of information	2			
Compensation of volunteers	2				

## Treatment of overdose and poisoning

Objective	Subject Matter	Competence		Teaching/Learning Method	Assessment/evidence of competence
		Knowledge	Skills		
To manage and advise on cases of overdose or poisoning	Mechanism of action of common and important poisons, including therapeutic drugs, drugs of abuse and some chemicals.	1		Clinical experience of treating poisoned patients	Observation by supervisor  <i>Tests of knowledge</i>
	General strategies for the management of poisoned patients, including resuscitation, decontamination, investigation, monitoring and antidotal treatment.	1*		Secondment to a poisons/toxicology centre  Taught course	
	Specific knowledge and experience of poisoning with acetaminophen, aspirin, tricyclic compounds, opioids and benzodiazepenes.	1*	A		

\* These aspects may not be required by some trainees who are not involved in acute medical intake

## **JOINT PROGRAMMES IN CLINICAL PHARMACOLOGY AND THERAPEUTICS, GENERAL (INTERNAL) MEDICINE AND A THIRD SPECIALTY**

### **Introduction**

It has been customary in the past for those undergoing higher specialist training in Clinical Pharmacology and Therapeutics to combine this with specialist training in General (Internal) Medicine alone. However, most of these trainees will eventually work in academic departments and it is some time since any NHS consultant posts were created for those who had undergone such combined training. Furthermore, several organ-based specialties are now appreciating the value of recruiting specialists who have experience in Clinical Pharmacology & Therapeutics. Such a breadth of training leads to a better qualified specialist with a deeper understanding of drug therapy, but also a specialist who has a firmer grounding in the principles of clinical investigation. Academic departments of Clinical Pharmacology & Therapeutics are also tending to specialise in an organ-based way in respect of their research activities.

The following programme sets out a way in which triple certification could be secured within seven years, using Respiratory Medicine as an example of an organ-based specialty. The programme could equally well apply to, for example, Gastroenterology, Renal Medicine or Endocrinology and Diabetes Mellitus. For cardiology, an eight year programme may be necessary.

### **Programme including Respiratory Medicine with Clinical Pharmacology and Therapeutics and General (Internal) Medicine**

#### **Year 1**

General (Internal) Medicine in a DGH with limited exposure to CPT or Respiratory Medicine. This year would count as one full year towards certification in General (Internal) Medicine.

#### **Year 2**

Clinical skills training in Clinical Pharmacology & Therapeutics and Respiratory Medicine. This year would count as one full year towards certification in each of these two specialties.

#### **Year 3**

Clinical skills training in Respiratory Medicine.

#### **Year 4**

Investigational skills training in CPT.

#### **Year 5**

Supervised research in Respiratory Medicine with a bias towards drug action and/or drug treatment. It should be noted that the relevance of the research year to training in Respiratory Medicine must be insisted upon. Otherwise, the training programme in Respiratory Medicine will be one year short.

**Year 6**

Clinical skills training in Respiratory Medicine and General (Internal) Medicine. At this stage experience in G(I)M would involve a lower commitment to on-take (at least two days per month averaged over the year, with at least ten patients admitted on each take day), the trainee to have ongoing care for approximately one third of these) and a minimum of one General (Internal) Medicine outpatient clinic each week. This year would count as a full year towards certification in each of the two disciplines.

**Year 7**

Clinical skills training in Clinical Pharmacology & Therapeutics and General (Internal) Medicine (at the lower level of commitment defined above). This year to count as a full year towards certification in each of the two disciplines.

In reckoning the contribution of elements in the training programme towards each specialty's requirements for awarding a CSST, years 2, 4, 5 and 7 would fulfil a four year requirement for a CCST in Clinical Pharmacology and Therapeutics. Years 2, 3, 5 and 6 would fulfil a four year requirement for a CCST in Respiratory Medicine. Years 1, 6 and 7, when added to two years' general professional training would fulfil the five year requirement for certification in General (Internal) Medicine.

The order of training in years 2-5 and of years 6 and 7 could be varied according to local requirements.